



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

94690d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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WARNING LETTER

NWE-25-04W

VIA FED-EX

April 19, 2004

Mr. Donald W. Barrett, Jr.
President
ITV Direct, Inc. / Direct Marketing Concepts, Inc.
100 Cummings Center, Suite 506E
Beverly, MA 01915

Dear Mr. Barrett:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your firm, ITV Direct, Inc. / Direct Marketing Concepts, Inc., located at 100 Cummings Center, Beverly, MA 01915 on February 11-13, 2004. During this inspection, our investigator collected labeling associated with your product Supreme Greens with MSM, including a brochure and customer letter that you include with customer orders. Our investigator also collected substantiation you provided for the claims made for your product Supreme Greens with MSM. In addition, on February 11, 2004, we reviewed labeling on your website at <http://www.todayshealth.com>. A review of your labeling indicates serious violations of the Act. You can find the Act and FDA regulations on the Internet through links on FDA's web page www.fda.gov.

Based on our February 11th review of your website <http://www.todayshealth.com>, we have determined that your product Supreme Greens with MSM, being offered for sale through the website on that date, was promoted for conditions that cause your product to be a drug under section 201(g)(1) of the Act. The claims on your website establish that your product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease.

Examples of some of the claims observed on your web site include:

- "What are the Results of an Unbalanced pH?... A number of health problems and degenerative conditions have been linked to highly acidic cell pH:
 - Cancer
 - Arthritis
 - Fibromyalgia
 - ...
 - Osteoporosis
 - High Blood Pressure
 - High Cholesterol
 - ...
 - Diabetes
 - Gout
 - Epstein Bar [sic]
 - ...
 - Heart Disease
 - Eczema
 - Psoriasis
 - Liver Disease
 - Hepatitis
 - Insomnia
 - Shingles
 - Attention Deficit Disorder (A.D.D.)
 - Allergies
 - Asthma

So How Do You Rebalance Your Cells [sic] pH levels ...?...Supreme Greens with MSM This naturally alkaline supplement balances body pH"

- "Supreme Greens was formulated by Dr. Alex Guerrero, a renowned physician who has focused his career on working with people with various degenerative diseases and chronic ailments. His breakthrough supplement has already helped thousands of people with cancer, diabetes, arthritis, lupus, fibromyalgia, chronic fatigue syndrome"

Moreover, your product is also a "new drug" as defined in Section 201(p) of the Act because it is not generally recognized as safe and effective for its intended uses. Under section 301(d) of the Act, new drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act. Furthermore, this drug is misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for this drug fails to bear adequate directions for use.

Your product is labeled as a dietary supplement. Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. FDA has published a final rule intended to

clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)). The manufacturer of a dietary supplement containing a "structure/function" claim in the product's labeling must have substantiation that the claim is truthful and not misleading.

The labeling of your product bears structure/function claims that include the following:

- "Supreme Greens with MSM is naturally alkaline helping to balance your body's pH"
- "Natural weight loss, Supreme Greens with MSM™ can help you lose weight easily and naturally"
- "Helps to control hunger and cravings."
- "Neutralize acidity. Heartburn, acid reflux ... may be a result of over-acidification."
- "May help to provide mental clarity"
- "Oxygenates the cells"
- "A powerful blood purifier and detoxifier"
- "A natural anti-aging formula"
- "Supreme Green with MSM helps you overcome this deficiency by providing you with the nutritional equivalent of 2 lbs. of fresh vegetables in every serving."

We have reviewed these claims and have concluded that they are not supported by reliable scientific evidence. Because these claims lack substantiation, they are false or misleading, and cause your product to be misbranded under sections 403(a)(1) and 403(r)(6)(B) of the Act.

In addition, your product label bears the following claim:

- "Each 3 capsule serving has the nutrition value of about 5-7 servings of vegetables."

We have reviewed this claim and determined that it is false or misleading, and causes your product to be misbranded under section 403(a)(1) of the Act. It is a violation of section 301(a) of the Act to introduce or deliver for introduction into interstate commerce any food, including a dietary supplement, that is misbranded.

This letter is not intended to be an all-inclusive review of your Internet websites nor other labeling and products marketed by your firm. The violations described above are not intended to be an all-inclusive list of violations concerning your firm and its products. You are responsible for ensuring that all products marketed by your firm are in compliance with applicable United States laws.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug

Administration without further notice. The Act provides for seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

You must notify this office, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. Copies of the revised labeling should also be submitted. If corrective action cannot be completed within 15 working days, state the reason(s) for delay and the time at which the corrections will be completed.

You should direct your reply to Patricia Murphy, Compliance Officer at One Montvale Avenue, Suite 4, Stoneham, MA 02180. If you have any question concerning this letter, please contact Ms. Murphy at 781-596-7758.

Sincerely,

A handwritten signature in black ink, appearing to read "Gail T. Costello", with a stylized flourish at the end.

Gail T. Costello
Director
New England District